REMARKS

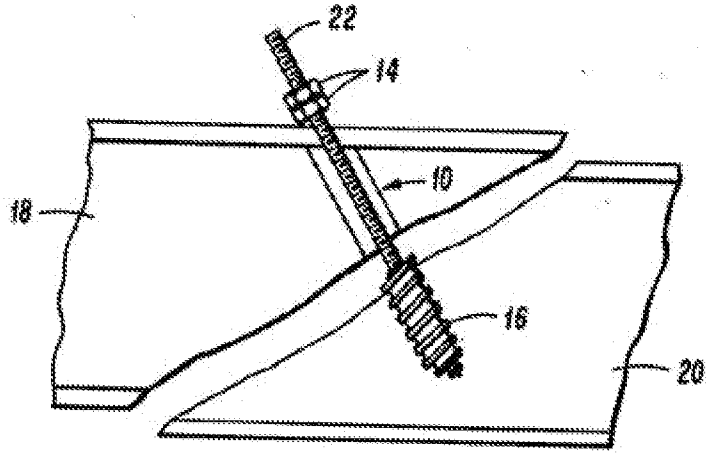
This is in response to the Office Action mailed on December 28, 2007, in which claims 1-38 were pending, and claims 8-10, 14, 16, 35 and 38 were withdrawn from consideration. Claims 1-7, 11-13, 15, 17-34, 36 and 37 were rejected over the prior art, either as anticipated by U.S. Patent No. 4,456,005 to Lichty ("Lichty") or as obvious in view of Lichty in combination with other prior art. As further explained below, Applicant traverses both rejections. Claims 1, 11, 14, 17, 18, 21, 22, 28 and 37 are amended to clarify the invention. The application containing pending claims 1-38 is in condition for allowance. Reconsideration and notice to that effect is respectfully requested.

Applicant respectfully thanks the Examiner for the telephone interview conducted February 6, 2008. The Examiner's application of claim language to Lichty was discussed, and Applicant explained how the claims did not read on Lichty in several respects. Applicant agreed to put such explanation in writing for the Examiner's consideration, but no further agreement was reached.

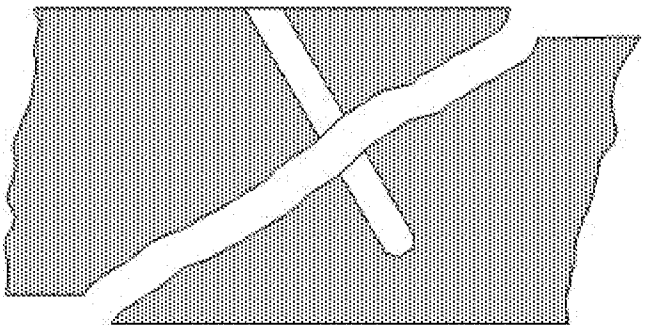
Claims 1-6, 11-13, 15, 17, 18, 21, 28-32 and 36 were rejected as anticipated by Lichty. Claims 7, 19, 20, 22-27, 33, 34 and 37 were rejected as obvious over Lichty and one or more other references. Claim 1 requires a compression engagement providing a shoulder extending at a substantial angle to the shaft axis for substantial contact with an exterior surface of the bone fragment. Independent claims 17, 18 and 21 include a similar limitation, and require the compression engagement be in contact with the exterior surface of the bone fragment during the healing duration. Claims 22, 28 and 36 also have, or are amended to have, a "contact with exterior surface" limitation. The Office Action stated, "Lichty discloses…a compression engagement (Fig. 2, ref. 14)… providing a shoulder (Fig. 2, bottom and side surface of ref. 14) extending at a substantial angle to the shaft axis for substantial contact with an exterior surface of the bone fragment (Fig. 2)."

Figure 2 of Lichty is reproduced below.

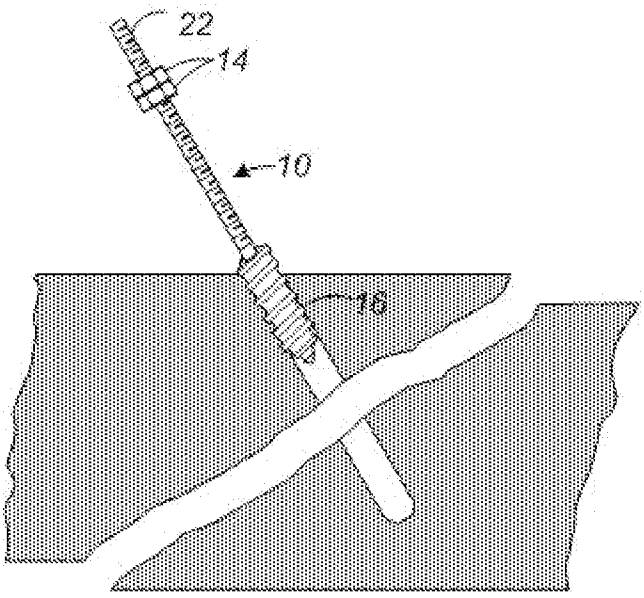
FIG 2



A first step in understanding the method of Lichty is to understand what this figure represents in terms of the bone structures which are not clearly shown. Namely, Lichty states, "a drill is used to bore an opening through the bone fragments which opening is slightly smaller in diameter than the major diameter of the thread on the body 16 of distal part 10. * * * Note that the boring occurs from one side of the bone and does not extend completely through to the opposite side." Col. 2, lines 57-65. In a cross-sectional view with the bone shaded to better show the drill hole formed in the Lichty bone fragment and anchor bone, this would look as follows:

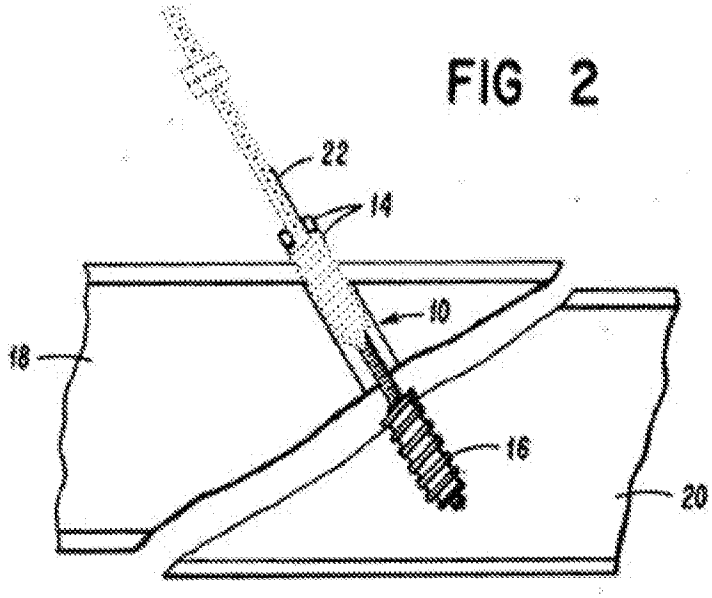


Lichty then states, "When the boring is completed, two nuts 14 are threaded a slight distance onto the upper shaft 22 of the distal part 10. By use of an appropriate wrench, the distal part 10 is then threaded into the bore opening completely through the proximal fragment 18 and into the distal fragment 20 until the body 16 has passed the fracture line." Col. 2, line 65 – Col. 3, line 4. A view showing this operation midway completed would look as follows:



Overlaying this earlier location of the device 10 on the drawing of FIG. 2 looks as follows:

FIG 2



Inspection of this sequence of drawings and this overlay makes several features of the Lichty device abundantly clear. Firstly, that the opening created, first by the drilling and then by the advancing of the anchor section 16, extends entirely through the bone fragment 18, i.e., through both cortical and cancellous bone of the fragment, regardless of whether or how this opening is depicted

in FIG. 2. Secondly, the nuts 14 are depicted with a diameter which is about the same or slightly smaller than the major diameter of the anchor section 16. The Lichty specification does not suggest that the nuts 14 should have any greater diameter than depicted. Thirdly, and most importantly, the nuts 14 are not intended to make contact with the bone, and, by virtue of falling within the "shadow" of where the anchor section has passed, never do make contact with the bone in the Lichty disclosed method.

While Lichty discloses nuts 14 which provide a shoulder, these nuts 14 are not a compressive engagement of the device because they do not contact the bone fragment and do not provide any force to the bone fragment. The Office Action statement that the bottom and side surfaces of the nuts make "substantial contact with an exterior surface of the bone fragment" is erroneous and is contrary to Figure 2 and the disclosed method of Lichty. Further note FIG. 3 of Lichty, wherein the bone fragment has not been moved toward the anchor bone. That is, the entire sequence and disclosure of Lichty makes clear that the compressive contact with the bone fragment is provided by the proximal section 12, not by the nuts 14. The nuts 14 serve exclusively to transfer torque to the distal section 10 and to transfer a compressive force from the distal section 10 to the proximal section 12 without the nuts 14 ever contacting the bone.

Claim 1 requires the compression engagement have a shoulder "for substantial contact with an exterior surface of the bone fragment." Claims 17, 18 and 21 include a similar limitation, and require the compression engagement be in contact with the exterior surface of the bone fragment during the healing duration. Nuts 14, which do not make contact with the bone fragment in the method of Lichty, do not fulfill this limitation. The rejection of claims 1-7, 11-13, 15, 17-34, 36 and 37, mistakenly relying on nuts 14 contacting the bone fragment, should be withdrawn.

Further, while proximal portion 12 of Lichty is a compressive engagement, it too does not make contact with an exterior surface of the bone fragment. Instead of the compressive contact with the exterior surface of the bone fragment taught and claimed by the present invention, Lichty relies on a threaded connection to transfer a compressive force from proximal portion 12 to the bone fragment 18: "By applying a suitable wrench to the hex head 24, proximal part 12 is threated (sic) into the proximal fragment 18 to a position such as shown in FIG. 3. * * * Both of nuts 14 as well as

hex head 24 extend outside of the skin surface, and after completion of the surgical procedure they are properly dressed with a sterile antibiotic dressing. * * * [E]ach of the two components of the device is securely threaded into the separated fragments of the bone." Col. 3, lines 6-8, 18-20, 31-33. The Lichty compressive force relies on the threaded connection between the proximal portion 12 and the bone fragment 18. If the bone fragment 18 is too thin or fragile to hold the threaded connection between the proximal portion 12 and the bone fragment 18, then no compression can be achieved by Lichty. The threaded connection between the proximal portion 12 and the bone fragment 18 occurs on the interior surface of the bone fragment, not on the exterior surface of the bone fragment as required in the present claims. There is no disclosure or suggestion in Lichty to have the device make contact with an exterior surface of any bone, much less to have a compression engagement make contact with an exterior surface of the bone fragment to apply a compressive force.

Independent claims 1, 17, 18, 21, 22 and 28 are amended to clarify another aspect of the inventive structure, that of the shoulder being wider than the major diameter of the threads of the bone anchor section. Independent claim 19 already required that the shoulder be at a diameter greater than the major diameter of the threads of the anchor section. This limitation is not disclosed or suggested by Lichty, wherein the nuts 14 and the proximal part 12 are both depicted at or smaller than the major diameter of the anchor threads. Claim 19 was rejected as obvious over Lichty in view of U.S. Patent No. 5,709,687 to Pennig. The Office Action stated, "Lichty in view of Pennig discloses the claimed invention except for the shoulder being at a diameter greater than the major diameter of the threads of the anchor section. It would have been an obvious matter of design choice to have constructed the shoulders as having a larger diameter than the threads of the anchor section, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art." To the contrary, the larger diameter of the shoulder is not a mere change in size, but rather is due to its novel and non-obvious function of contacting an exterior surface of the bone fragment to apply a compressive force. Further, Lichty teaches directly against such a larger diameter. Lichty specifically states, "Both of nuts 14 as well as hex head 24 extend outside of the skin surface..." Col. 3, line 18-19. Lichty then touts the advantage of "The device of the invention has several advantages over many prior art

external fixation devices. It is technically simpler to use, and it has less hardware exposed above the skin surface, thus minimizing the risk of infection." (emphasis added). That is, Lichty teaches that with both of nuts 14 as well as hex head 24 extending outside of the skin surface, both of nuts 14 and hex head 24 should be made as small as possible to minimize the risk of infection. Making either nuts 14 and/or hex head 24 of a larger diameter would be directly contrary to this teaching of Lichty, and would not be obvious.

As clarified in the telephone interview, the Office Action is considering the entire machine threaded upper shaft 22 of Lichty to be the "bone exterior section". The entire machine threaded upper shaft 22 of Lichty clearly meets the "at least one third of the total length of the device" limitation. However, claim 1 requires the compression engagement be located "on a distal end of the bone exterior section". Claim 18 includes a similar limitation. As shown in FIG. 2 of Lichty, nuts 14 are on the proximal side of the upper shaft 22, perhaps ¼ to 1/3 of the way to the distal end of the upper shaft 22. The distal end of upper shaft 22 is where upper shaft 22 meets the body 16. Lichty does not disclose or suggest placing nuts 14 at the distal end of upper shaft 22, and does not meet the limitation that the compression engagement be located "on a distal end of the bone exterior section". The rejection of claims 1-7, 11-13, 15 and 18 should be withdrawn for this reason as well.

As a separate limitation, claim 1 requires the major diameter of the threads of the anchor section be greater than a shaft diameter of the non-engaging fragment section. With regard to this limitation, the Office Action stated, "Lichty discloses… a non-engaging fragment section (Fig. 2, proximal portion of ref. 16)". However, the proximal portion of body 16 of Lichty is the same profile as the distal portion of body 16, both having anchor threads of the same size. In the method of Lichty, the entire body portion 16 is advanced into the anchor bone and engages the anchor bone. The proximal portion of body 16 is neither "non-engaging" nor a "fragment" section.

Claim 1 further requires "screwing the device such that the bone anchor section advances into an anchor bone with the fragment section in the bone fragment and with the bone exterior section extending outside the bone and with the compression engagement in contact with an exterior surface of the bone fragment to provide a compressive force on the bone fragment toward the anchor bone, thereby connecting the bone fragment to the anchor bone for a healing duration and extending out of

the bone during the healing duration". Claims 17, 18, 21, 22 and 28 include similar limitations. As shown in FIG. 4, Lichty teaches that the proximal portion of body 16 is within the anchor bone for the healing duration. The proximal portion of body 16 is not in the bone fragment at any time that the device is making contact with the bone fragment 18. The rejection of claims 1-7, 11-13, 15, 17-34 and 36 should be withdrawn for these reasons as well.

Claim 5 was rejected as anticipated by Lichty. Claim 5 requires that the inside diameter of the internal threads on the compression engagement is smaller than the non-engaging fragment section such that the internal threads on the compression engagement cannot advance onto the non-engaging fragment section. While the inside diameter of the internal threads on the Lichty nuts 14 is smaller than the body 16 such that the internal threads on the nuts 14 cannot advance onto the body 16, Applicant notes that the machine threaded upper shaft 22 has threads of the same size throughout its entire length. If part of machine threaded upper shaft 22 of Lichty were considered the non-engaging fragment section, then claim 5 would clearly avoid such a consideration.

Claim 11 was rejected as anticipated by Lichty. Claim 11 requires that the shaft of the non-engaging fragment section is substantially smooth and cylindrical. The Office Action referred to Figure 2 of Lichty as disclosing this limitation, which was discussed during the interview. The Examiner stated a viewpoint that the anchor threads 16 have a shaft which is substantially smooth and cylindrical, which Applicant believes is an overly broad reading of this limitation. The Examiner indicated that a "nonthreaded" limitation might better explain the concept, and Applicant agreed to this change, noting that "nonthreaded" was broader than "substantially smooth and cylindrical" and that anything which is externally threaded is not "substantially smooth and cylindrical". Figure 2 of Lichty shows the entire length of the distal part 10 as being threaded, either the "body 16 that is externally threaded" or the "upper shaft 22 that is also externally threaded" Col. 2, line 13-14 and 17-18. Because Lichty does not show any nonthreaded portion of distal part 10, the rejection of claim 11 should be withdrawn for this reason as well.

Claims 12 and 13 were rejected as anticipated by Lichty, and claims 26 and 27 were rejected as obvious over Lichty in view of Huebner. Claims 12 and 26 require the threads on the bone anchor section be self-tapping distally for insertion, and claims 13 and 27 require the threads on the bone

anchor section be self-tapping proximally for removal. Self-tapping threads are neither disclosed nor suggested in Lichty, which merely shows a continuous thread form. The rejection of claims 12 and 13 should be withdrawn for these reasons as well. Self-tapping threads are disclosed in Huebner (see notch 37) only distally for insertion, and the rejection of claim 27 should be withdrawn.

Claim 15 was rejected as anticipated by Lichty. Claim 15 requires that the bone anchor section ends in a distal drill tip adapted for insertion in bone without pre-drilling, and that the advancing and screwing acts be performed without pre-drilling. No method without pre-drilling is disclosed or suggested by Lichty, which expressly teaches pre-drilling. ("a drill is used to bore an opening through the bone fragments which opening is slightly smaller in diameter than the major diameter of the thread on the body 16 of distal part 10. The drill is used to bore an opening through both the proximal fragment 18 and the distal fragment 20 at approximately a right angle to the line of the fracture." Col. 2, lines 57-63). The rejection of claim 15 should be withdrawn for this reason as well.

Claim 19 was rejected as obvious over Lichty in view of Pennig. Inter alia, claim 19 requires the non-engaging fragment section to have a smooth outer profile. No explanation was given in the Office Action as to why the combination of Pennig with Lichty would change the proximal portion of body 16 of Lichty to have a smooth outer profile. The rejection of claims 19 and 20 should be withdrawn for this reason as well.

Claim 29 requires that, with the bone anchor section advanced into the bone fragment but prior to the act of further screwing the device into the anchor bone, the bone exterior section be manipulated to reposition or bias the bone fragment relative to the anchor bone. Claim 30 requires, after the manipulating act, that the bone exterior section be held in a desired alignment during the further screwing act. Claims 29 and 30 were rejected as anticipated by Lichty. However, Lichty discloses a predrilling method, and expressly teaches "After the fracture has been reduced so that the bone fragments are proximated and are temporarily held in a properly aligned position, a drill is used..." Col. 2, line 55-57. As such, the method of Lichty could not possibly use the "joy-sticking" method of repositioning or biasing the bone fragment as an intermediate step in the implantation of the device. Claims 29 and 30 should be allowed for these limitations as well.

Claim 33 was rejected as obvious over Lichty, and claim 20 was rejected as obvious over Lichty in view of Pennig. The Office Action stated, "The [Lichty] device further comprises a pointed proximal tip, and further comprising using the pointed proximal tip for drilling through bone in a reverse direction." Such Office Action statement is not understood, as the Lichty device shows a flat, blunt proximal tip as its only embodiment. The Office Action also stated, "It would have been obvious to a person having ordinary skill in the art to have reversed the steps of Lichty, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art." Such Office Action statement is not understood. Lichty has no disclosure or suggestion to introduce its device 10 to the bone in the opposite direction – i.e., from the bottom in FIG. 2. Lichty expressly teaches the opposite, stating, "Note that the boring occurs from one side of the bone and does not extend completely through to the opposite side." Col. 2, line 63-65. Claim 33 requires the directional opposite of this teaching of Lichty, namely, the screwing act and the further screwing act occur in a reverse direction such that the device is inserted into the anchor bone prior to engaging the bone fragment, while the moving of the compression engagement axially on the elongated shaft occurs in a forward direction, opposite to the direction the device was introduced to the bone. If the device is inserted in the direction opposite to advancement of the compression engagement, an opening through the bone necessarily extends completely through to the opposite side of both the bone fragment and the anchor bone. Lichty simply does not contemplate advancing the distal part 10 from the bottom and the proximal part 12 from the top or opposite side of the bone. Claim 20 requires the device further comprise a pointed proximal tip, and further comprising using the pointed proximal tip for drilling through bone in a reverse direction. The rejection of claims 20 and 33 should be withdrawn as the prior art does not disclose or suggest these limitations as well.

The application containing pending claims 1-38 is in condition for allowance. Reconsideration and notice to that effect is respectfully requested. The Examiner is invited to contact the undersigned at the telephone number listed below if such a call would in any way facilitate allowance of the application.

Respectfully submitted,

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